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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/689,475

10/20/2003

Dean J. Secrest

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07/21/2009

CALFEE HALTER & GRISWOLD, LLP

800 SUPERIOR AVENUE

SUITE 1400

CLEVELAND, OH 44114

EXAMINER

LANDRY II, GERALD ERNEST

ART UNIT

PAPER NUMBER

3763

NOTIFICATION DATE

DELIVERY MODE

07/21/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@calfee.com

dcunin@calfee.com

Office Action Summary	Application No. 10/689,475	Applicant(s) SECRET ET AL.	
	Examiner GERALD LANDRY II	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/12/2003, 07/21/2008, 04/17/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. A restriction was improperly issued by the examiner on 6/29/2009 due to a discrepancy in filing of the claims by the applicant. During a phone call on 07/06/2009 with William Johnston the improper restriction was pointed out and is withdrawn by the examiner.

Specification

1. The disclosure is objected to because of the following informalities: Page 2 line 12 reads “may be forced to withdrawn”.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 18-26 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,210,377 to Ouchi.

Regarding claims 18-26, Ouchi teaches fabricating a helically wound wire spring **(912)** coated with a low friction material to form an internal passageway; determining a desired length of a guide housing; cutting the helically wound wire spring to an initial length to form a guide housing, wherein the initial length is greater than the desired length; assembling the device comprising the steps of: providing a support body **(416)**; inserting at least a portion of a motion transmitting unit **(11)** within the body, the unit comprising a first end portion proximal to the support body and a second end portion remote from the support body, wherein the motion transmitting unit is movable relative to the support body; providing an agent delivery system

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comprising a needle (**512**) having a hollow elongated body, a first end for extending into a subject and a second end fixed to the motion transmitting member, and structure defining a conduit between the support body and the needle; fixing the needle to the motion transmitting unit; and sliding at least a portion of the motion transmitting unit adjacent the needle within the guide housing; and conditioning the guide housing prior to use of the device by manipulating the guide housing to flatten the low friction material between the wire spring, so that the initial length shortens to essentially the desired length; wherein the step of conditioning the guide housing comprises repetitively coiling the guide housing in an alternating pattern until the initial length shortens to essentially the desired length; wherein the step of conditioning the guide housing comprises axially compressing the guide housing under force until the initial length shortens to essentially the desired length; cutting a wire spring coating with a friction reducing material to form a guide housing of an initial length; assembling the device comprising the steps of: providing a support body; inserting at least a portion of a motion transmitting unit within the body, the unit comprising a first end portion proximal to the support body and a second end portion remote from the support body, wherein the motion transmitting unit is movable relative to the support body; providing an agent delivery system comprising a needle having a hollow elongated body, a first end for extending into a subject and a second end fixed to the motion transmitting member, and structure defining a conduit between the support body and the needle; fixing the needle to the motion transmitting unit; and sliding at least a portion of the motion transmitting unit adjacent the needle within the guide housing; and treating the guide housing prior to use of the device by manipulating the guide housing to flatten at least a portion of the friction reducing material, whereby the initial length shortens to a desired length; wherein the

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step of treating the guide housing comprises repetitively coiling the guide housing in an alternating pattern; wherein the step of conditioning the guide housing comprises axially compressing the guide housing under force; selecting a helically wound wire spring coated with a low friction material; determining a desired length of the guide housing; cutting the helically wound wire spring to an initial length, wherein the initial length is greater than the desired length; and conditioning the guide housing by manipulating the guide housing to flatten the low friction material between the wire spring, whereby the initial length shortens to essentially the desired length; wherein the step of conditioning the guide housing comprises repetitively coiling the guide housing in an alternating pattern until the initial length shortens to essentially the desired length; wherein the step of conditioning the guide housing comprises axially compressing the guide housing under force until the initial length shortens to essentially the desired length **(invention substantially as claimed is taught in column 17 line 65 - column 19 line 16 and figures 45-47)**. Also note that the claimed phrases above are being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113.

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please refer to form PTO-892.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to GERALD LANDRY II whose telephone number is (571)270-7409. The examiner can normally be reached on M-F, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GEL/

Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763

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